PATENT SPECIFICATION

(11) 1 463 107

(21) Application No. 25866/74 (22) Filed 11 June 1974
(31) Convention Application No. 3740/73
(32) Filed 19 June 1973 in
(33) Australia (AU)
(44) Complete Specification published 2 Feb. 1977
(51) INT CL² G02C 7/04
(52) Index at acceptance G2J S6AX S6B S6C

(19)

1 463 107

(54) SOFT CONTACT LENSES

(71) We, JOHN PHILLIP FRITH STRACHAN, of 12 Laurel Grove, Blackburn, in the State of Victoria, Commonwealth of Australia, and VICTOR STANLEY LOWE, of 4—A Montrose Street, Hawthorn East, in the State of Victoria, Commonwealth of Australia, both Australian Citizens, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to soft contact lenses composed of a soft flexible material as opposed to hard lenses made of glass or polymethylmethacrylate. Such lenses are conveniently made of a refractive gel-like polymeric material.

The Practitioner, in prescribing lenses, usually uses a set of lenses of varying sizes to determine the lens type most suitable for the particular patient. Previously, fitting sets of hydrophilic soft lenses have used back surface radii varying every 30/100 mm starting with 7.5 mm or 7.8 mm then 8.1 mm then 8.4 mm then 8.7 and sometimes 9.0 mm. The overall sizes of the round lens combined with the radii varied and were 13.00, 13.50, 14.00, 14.50 and 15.00 mm, such as

Back Radius	*Overall Size*				
7.5	13.00	13.50			
7.8	13.00	13.50	14.00		
8.1		13.50	14.50		
8.4		13.50	14.00	14.50	15.00
8.7		13.50	14.00	14.50	15.00

These lenses were either made in Bionite/Naturalens (Registered Trade Mark) polymer (2-hydroxyethyl-methacrylate) and P.V.P. (polyvinyl pyrrolidine), or hema,2 hydroxyethyl-methacrylate or EGMA (ethylene glycol methacrylate) by spin casting, polymerisation in a rotating spindle in a spherical cup or by lathe generated spherical or parabolic surfaces.

The lenses are fitted flatter than the general topography of the human cornea, according to certain rules and clinical experience and the ideal fitting is chosen by reference to the Keratometer readings of the front surface of the lens on the eye, the subjective refraction and the use of such instruments, for the examination of the external eye surfaces and its media, as the retinoscope, ophthalmoscope and slit lamp biomicroscope.

Soft flexible lenses when applied to the surface of the cornea fit flatter, i.e. when the lens is such that before being applied to the cornea its shape is flatter than the shape of the cornea, conform to the surface of the cornea by wrapping and duplicating the surface shape of the cornea.

If the cornea is nearly spherical the soft lens duplicates this and the effect of the lens is the same as for a hard lens.

If the cornea posesses astigmatism because its surface is toric, the soft flexible lens duplicates the corneal shape and its front surface becomes toric. This results in residual astigmatism or left over uncorrected astigmatism in the visual correction and results in loss of clear vision. Such a situation never arose in the use

of hard lenses as they retained their shape and any residual astigmatism left with a hard lens is due to other optical elements of the eye.

It is an object of this invention t pr vide a soft lens which can correct such residual astigmatism as well as defects caused by other pr perties of the refracting elements of the eye.

To this end, the present invention provides a soft optical contact lens or a dehydrated lens hydratable to form a soft optical contact lens for use in correcting astigmatism which has at least one of its front or back surfaces toric and is stabilized by. single truncation (as hereinafter defined), double truncation (as hereinafter defined) or prism ballast (as hereinafter defined) in conjunction with single or double truncation. By the term soft lens is meant a lens of soft flexible material which is able to conform to the surface of the cornea and exhibits the property that if the back surface of the lens is not identical to the face of the cornea then the shape of the cornea is duplicated on the front surface of the lens.

Throughout this specification certain technical terms are used, and these are defined as follows:

TORIC: A surface generated with two spherical surfaces superimposed. The radius of curvature in one meridian being different, at right angles or any angle greater than zero and less than 90°, to the radius of curvature in the other meridian. The two radii being of different length.

STABILIZED: A lens is said to be stabilized if it orientates on the eye about a constant axis.
A lens is stabilized by—
1. Single truncation; (see Figure 1)
2. Double truncation; (see Figure 2)
3. Prism ballast; (see Figures 3A and 3B)
4. Prism ballast with single or double truncation. (see Figures 5A to 5C).

TRUNCATION: Is a term where a spherical circumference has a part cut off the lens in the line of a chord. They can be either vertical or horizontal, the vertical truncations being preferred where the lens is thicker.

DOUBLE TRUNCATION: Where two parallel chords denote the line of material removed (see Figure 2).

SINGLE TRUNCATION: Where one chord denotes material removed (see Figure 1). In each case the new exposed edge/s are polished to a round cross-section.

PRISM BALLAST: Where the optical centre is displaced and the cross-section is in the form of a prism with the base down on the eye (see Figures 3A and 3B).

The terms vertical and horizontal refer to the orientation of the lens on the eye of an erect person. Generally the lens is described in relation to vertical and horizontal axes as shown in Figures 1 and 2.

The lenses according to the present invention preferably take any one of the following forms:

1) A stabilized soft lens having a toric back surface and a spherical front surface (see Figures 4A, 4B and 4C, in which stabilization is by a single truncation). Stabilization can also be achieved by double truncation aligned in a horizontal or vertical configuration.

2) A stabilized soft lens having a bifocal front surface and a toric back surface. The front surface is composed of a peripheral portion of one radii and a centre of a second radii. This lens is illustrated in Figures 5A—5C where stabilization is by single truncation.

3) A soft lens stabilized by truncation having both front and back surfaces toric, i.e. bitoric. Thus, there are four radii, two for each surface, one being vertical and the other being horizontal.

4) A soft lens stabilized by truncation having a spherical back surface and a toric front surface. (This is the reverse of 1.).

5) A soft lens stabilized by truncation having a toric bifocal back surface and a spherical front surface. That is, the radii for the peripheral portion of the back surface are different in the vertical or horizontal directions and similarly the centre of the back surface also has different radii in both directions whereas the front

surface being spherical has the same radius in both directi ns.

The present invention uses a trial fitting set quite different to that previously used. Previous fitting sets have used several fixed radii, each having a range of diameters. The preferred set provided in conjunction with the present invention has a comm n diameter initially of 13.5 mm. The back surface is spherical and the radii change from 8.00 to 9.8 mm in 10/100 mm graduations. The front surface is also spherical. All trial lenses have a centre thickness of 0.25 mm on hydration and a power of −3.00 dioptres. If a plus power correction is required, then plus power lenses must be used.

In Figures 3B, 4B and 4C and 5B and 5C r^1 refers to internal radii and r^2 to external radii. Figures 4B and 5B show a vertical cross section and the radii of curvature along the vertical axis while Figures 4C and 5C show the same details in a horizontal cross section. Further, Figures 5B and 5C illustrate the variation in the outer radii of curvature r^2 in a bifocal lens.

In making a lens according to this invention, the back and front surfaces are preferably formed from a disc of dehydrated gel polymer and then hydrated to form the wet soft lens. In forming the lens in the dehydrated state, note must be taken of the 20% dimension change which occurs on hydration.

The clinical method used in this invention is as follows:

A Keratometer (or ophthalmometer) is used to measure the cornea to determine its power, radius and the angle of alignment of the power and radius. In this way, a reading of the expected corneal astigmatism can be obtained and compared to that of the spectacle prescription. Also, the Keratometer can be used to read the front surface of the soft trial lens on the cornea to confirm the alignment of the lens to the cornea and to compare the astigmatism of the front surface of the lens and the radii of the front surface when the lens is on the cornea. The Keratometer readings are used in both the dioptre and millimetre scales.

Trial lenses as described above are fitted to the eye in sequence to determine the correct fit of the flatter meridian of the cornea. The flattest lens which retains a regular wrapping of the cornea is selected. The estimated best fit lens (EBF) is determined from the Keratometer readings. Two basic tests are carried out with this lens.

1) The Keratometer is used to determine the regularity of the front surface of the lens, the radii in each meridian of the assumed toric surface and the astigmatism which is attributed to over refraction.

2) An accurate over refraction (subjective) test is carried out to determine the total power required to correct the eye and the value of the astigmatism.

When there is close correlation between the astigmatism mentioned in the spectacle refraction, the Keratometer dioptre readings, the expected corneal astigmatism, the over refraction astigmatism and the astigmatism of the front surface of the lens measured by the Keratometer, it is possible that a lens with a toric back surface in the same proportion in each meridian and a spherical front surface of the appropriate power will correct the eye's ametropia.

A radius to fit the steeper meridian of the cornea is chosen directly by reference to the radius of the cornea and not by trial and comparison. The lens is manufactured with a toric back surface suitable to the astigmatism of the cornea, having a front surface constructed as part of a sphere, the radius being chosen to correct the ametropia of the eye. The lens is stabilized by either single or double truncation, or single truncation with prism ballast along a line in relation to the meridians of the toric surface and the truncation is aligned by the lower lid.

Where the cornea shows a spherical reading with the Keratometer but there is a significant value of astigmatism in the spectacle correction the astigmatism is from elements within the eye and not the cornea.

To solve this problem, there is prescribed a lens constructed with a spherical back surface and a toric front surface and stabilized by truncation (single or double truncation) along a line such that the contour of the lower lid aligns the front toric surface along a meridian suitable to correct the residual astigmatism. Alternatively, the back surface can be toric and the front surface spherical, as the toric back surface will be induced on the front surface when the soft lens is on the eye. In both cases, the effect is to eliminate this astigmatism due to parts of the eye other than the cornea.

If there is a significant difference between the astigmatism indicated in the spectacle power and the Keratometer dioptre readings, then there are contributors to astigmatism from both the cornea and other refracting surfaces of the eye.

Where the eyes derive part of the astigmatism from the toric nature of the

corneal surfaces and part from other elem nts of the eye the lens is constructed with bitoric surfaces. The back surface is made toric to correspond to the ideal fitting of the toric cornea and the front surface is made toric to correspond t the astigmatism not corrected by the back surface of the lens. That is, the astigmatism from other refracting elements f the eye.

Before a prescription can be written, the angle of the middle third of the lower eyelid adjacent to the cornea is measured. This angle determines the angle that the straight truncated edge of the lens is moved to when in position on the eye. The toric back surface is chosen to correspond to the corneal astigmatism when the truncated lens is orientated by the lower lid.

The prescription given must include the two radii of the back surface and if necessary the radii of the front surface in mm, and their meridian angle, the number and amount of truncations, the overall size of the lens in millimetres along each meridian, and the calculated power along the flatter meridian of the lens in its hydrated state.

Where the front surface is bifocal (spherical) the prescription will also include the diameter and the power of the segment for distance viewing and the position and the power of the segment for near reading and the power.

The lens is stabilized by single or double truncation, or single truncation with prism ballast along a line to orientate the toric surfaces with the corresponding elements of the eye.

A stabilized lens can be constructed with spherical back surface where the cornea is nearly spherical or with a toric back surface if the cornea is astigmatic. The front surface can be made as a bifocal or multi-focal surface with stabilization by truncation to orientate the lens vertically on the cornea so that when looking forward the distance correction is provided and when looking down the near correction is provided so as to produce a bifocal correction.

A bifocal or multi-focal back surface can be so constructed that when the shape of the back surface is brought into contact with the eye, the front surface has its shape altered to a value which gives a bifocal/multi-focal power.

In manufacturing the lens, the radii are reduced by a factor (e.g. 1.2) to give their values in the dehydrated state. Similarly, the centre thickness is determined to give the correct hydrated value.

A toric surface is generated in the conventional manner used in the generation of lenses in hard acrylic materials. The lenses are truncated to the prescription and a spherical or bifocal spherical front surface is generated to correct the basic ametropia. The toric surfaces are formed with radii to 1/100 mm. accuracy. It must be borne in mind that inaccuracies are magnified in the hydrated state by about 20% depending on the material used to form the lens.

There will now be described a number of case histories and the resultant prescriptions in which the measurements given in the final prescriptions have been rounded to the nearest 1/20 m.m.

Example 1.

This is a case of "with the rule" astigmatism where the flatter curvature of the cornea is along the horizontal meridian.

The spectacle refraction is

Right eye	Left eye
+2.00/−4.00×15°	+1.75/−3.50×172°

The Keratometer readings (K) were:

R. 42.50 dioptres			L. 43.12 dioptres		
39.25	"	at 12°	39.68	"	at 170°

or Keratometer in m.m.

7.965 m.m.		7.918 m.m.	
8.654 m.m.	at 12°	8.518 m.m.	at 170°

The astigmatism to be expected from the cornea is

R. −3.25×12°	L. −3.44×170°

The estimated best fitting trial lens is determined using a factor of 1.16 for each meridian

R. 9.24 adjusted to 9.25	L. 9.18 adjusted to 9.20
10.03 " " 10.0	9.88 " " 9.90

With a spherical trial lens of 9.7 m.m./plano/13.50 m.m.°/s.

Right y over refraction is 1.50/–3.50x15° 'K' (39.44 (36.81 at 12

Astigmatism expected from front surface is 2.63x12° with spherical trial lens of 9.6 m.m./plano/13.50 m.m.°/s.

Left eye over refraction is 1.75/–.3.25x172° 'K' (38.81 (36.81 at 170

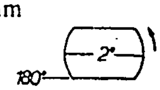
Astigmatism expected from front surface is 2.00x170.

This establishes that there is insignificant residual astigmatism due to other refractory elements of the eye. The flattest lens to remain stable is R 9.7/plano/13.50 L 9.6/plano/13.50. The angle of the lower lid of each eye is 10°.

The prescription is therefore

R_x R 9.7 at 2° (D.T. 1 mm at 180°
8.9 at 92°
°/s 13.5x11.5 mm

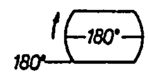
power +1.50 D



(Rotates 10° anticlockwise due to lower lid angle)

R_x L 9.6 at 180 D.T. 1 mm at 180°
8.9 at 90
°/s 13.5x11.5 mm

power +1.75 D.



(Rotates 10° clockwise due to lower lid angle).

Example 2.

This is a case of "against the rule" astigmatism where the flatter meridian is vertical.

Spectacle refraction

R –3.50/–2.00x95° L –3.25/–2.00x75°

Keratometer Readings
Dioptres

R 43.75	L 44.06
45.75 @ 5°	46.37 @ 165°

Millimetres

R 7.714	L 7.660
7.377 @ 5°	7.268 @ 165°

Expected Astigmatism from the Cornea

–2.00x95° –2.31x75°

Using a Factor of 1.16 to arrive at the Estimated Best Fit for each meridian

R 7.714x1.16=8.948 @ 95°	L 7.660x1.16=8.886 @ 75°
7.377x1.16=8.557 @ 5°	7.268x1.16=8.443 @ 165°

Trial Lens

R 8.9 mm –3.00 D. 13.50 mm L 8.9 mm –3.00 D 13.50 mm

Over Refraction

R Add 0.–50/–2.00x95° L Add –0.25/–2.25x75°

'K' Front Surface of Trial Lens

R 40.81	L 41.06
42.73 @ 5°	43.37 @ 165°

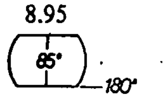
Astigmatism Due to Front Surface of Lens

R –1.92x95° L –2.31x75°

Prescription

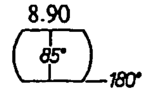
R_x R 8.95 @ 85° 8.55 @ 175°
D.T. 1 mm
O.S. 13.50 @ 175°
11.50 @ 85°
Power –3.50 D. @ 85°

8.95



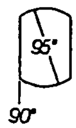
R_x L 8/90 mm @ 85° 8.45 mm @ 175°
D.T. 1 mm
O.S. 13.50 mm @ 175°
11.50 mm @ 85°
Power –3.25 D. @ 85°

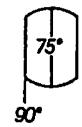
8.90



Or

R 8.95 @ 95° 8.55 @ 5°	L 89 mm @ 75° 8.45 mm @ 165°
D.T. 1 mm	D.T. 1 mm
O.S. 13.50 @ 95°	O.S. 13.50 @ 75°
11.50 @ 5°	11.50 mm @ 165°
Power −3.50 D.	Power −3.25 D.





The second prescription is desirable where high astigmatism exists and results in a thick lens. The truncation on the vertical edges ensures that the lens is not uncomfortable on the eye as these thick edges do not confront the eyelids. Such vertical truncation can be used with any prescription if desired.

Example 3.

This is another case of "with the rule" astigmatism.

Spectacle Refraction

R −2.00/−3.75x5° L −3.00/−2.00x5°

Keratometer Readings
Dioptres

R 47.00	L 46.56
44.00 @ 5°	44.44 @ 5°

Millimetres

R 7.181	L 7.248
7.670 @ 5°	7.594 @ 5°

Expected Astigmatism from the Cornea

−3.00x5° −2.12x5°

Using a Factor of 1.16 to arrive at the Estimated Best Fit for each Meridian

R 7.181x1.16=8.329 mm @ 95°	L 7.248x1.16=8.408 mm @ 95°
7.670x1.16=8.897 mm @ 5°	7.594x1.16=8.809 mm @ 5°

Round Off to Nearest 0.05 mm Division

R 8.35 @ 95°	L 8.40 @ 95°
8.90 @ 5°	8.80 @ 5°

Trial Lens Used

R with 8.9 mm −3.00 D. 13.50 mm L with 8.80 mm −3.00 D. 13.50 mm

Over Refraction

Add +1.00/2.00x5° Add Plano/−1.75x5°

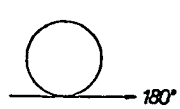
Keratometer Reading of the Front Surface of the Trial Lens on the Cornea

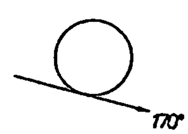
R 44.31	L 43.68
40.94 @ 2°	41.56 @ 5°

Astigmatism in Over Refraction Due to Front Surface of Trial Lens

R −3.37x2° L −2.12x5°

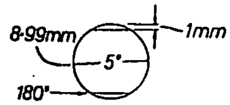
Measure Angle of the Middle Third of the Lower Lid





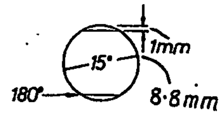
Prescription

R_x R 8.90 mm @ 5° 8.35 mm @ 95°
D.T. 1.0 mm
O.S. 13.50 @ 5°
11.50 mm @ 95°
Power –2.00 @ 5°



No rotation expected

R_x L 8.80 mm @ 15° 8.40 mm @ 105°
D.T. 1.0 mm
O.S. 13.50 mm @ 15°
11.50 mm @ 105°
Power –3.00 @ 15°



10° clockwise rotation expected on the eye

WHAT WE CLAIM IS:—

1. A soft optical contact lens or a dehydrated lens hydratable to form a soft optical contact lens for use in correcting astigmatism which has at least one of its front or back surfaces toric and is stabilized by single truncation (as hereinbefore defined), double truncation (as hereinbefore defined) or prism ballast (as hereinbefore defined) in conjunction with single or double truncation.

2. A lens as claimed in Claim 1 in which the back surface is toric and the front surface is spherical.

3. A lens as claimed in Claim 1 in which the front surface is toric and the back surface is spherical.

4. A lens as claimed in Claim 1 in which the front surface and the back surface are both toric.

5. A lens as claimed in Claim 1 in which the front surface is bifocal and the back surface is toric.

6. A lens as claimed in Claim 1 in which the front surface is spherical and the back surface is toric and bifocal.

7. A method of correcting corneal astigmatism comprising determining the toric surface of the cornea and preparing a soft optical contact lens having a toric back surface and a spherical or bifocal front surface and which is stabilized by single truncation (as hereinbefore defined), double truncation (as hereinbefore defined) or prism ballast (as hereinbefore defined) in conjunction with single or double truncation.

8. A method of correcting astigmatism comprising determining (1) the toric surface of the cornea, (2) the astigmatism due to the cornea and (3) the astigmatism due to the other refractory elements of the eye and then preparing a soft optical contact lens having a toric surface on either one or both of the front and back surfaces, the toric surface being such as to correct the astigmatism of the eye, and being stabilized by single truncation (as hereinbefore defined), double truncation (as hereinbefore defined) or prism ballast (as hereinbefore defined) in conjunction with single or double truncation.

9. A lens as claimed in Claim 1 and substantially as specifically described herein with reference to Examples 1, 2 or 3.

10. A lens as claimed in Claim 1 and substantially as specifically described herein with reference to Figure 1 or Figure 2 or Figures 4A, 4B and 4C or Figures 5A, 5B and 5C.

11. A method of making a lens as claimed in Claim 1 and substantially as specifically described herein.

KILBURN & STRODE,
Chartered Patent Agents.
Agents for the Applicants.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa, 1977. Published by the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

FIG.1.

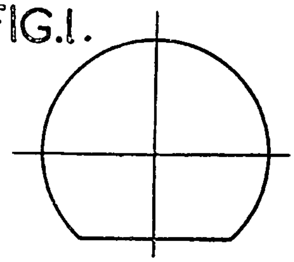


FIG.2.

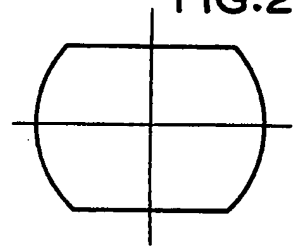


FIG.3A.

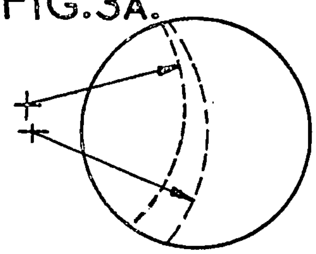


FIG.3B.

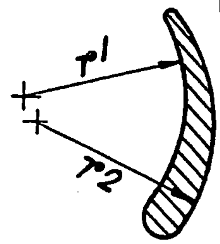


FIG.4A

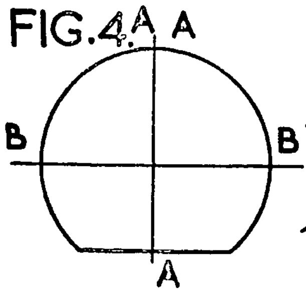


FIG.4B.

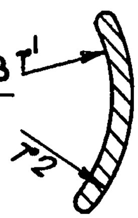


FIG.4C.

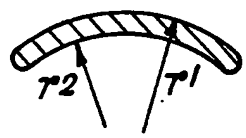


FIG.5A

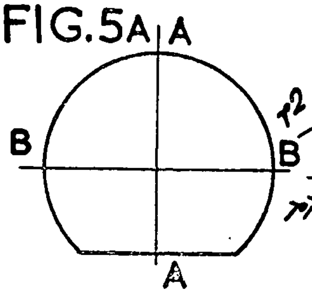


FIG.5B.

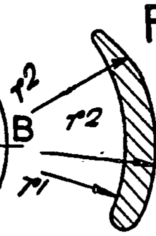


FIG.5C.